DIABETES HBA1C {POOR CONTROL}

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Contents

HRSA CCM: DIABETES HBA1C {POOR CONTROL}

The goals of this module are to provide a detailed overview of the HRSA's Core Clinical Measure, **Diabetes-HbA1c {Poor Control}**, hereafter called **Diabetes HbA1c**; outline the intended use for this measure, and highlight the benefits of implementing this measure into an organization's quality improvement (QI) program.

Measure Description

Name	Description	Numerator	Denominator	Source	Reference
Diabetes HbA1c	Percentage of patients aged 18 through 75 years with type 1 or type 2 diabetes mellitus who had a most recent hemoglobin A1c (HbA1c) greater than 9 percent	Number of patients from the denominator whose most recent hemoglobin A1c level during the measurement year is greater than 9 percent	Number of patients aged 18 through 75 years of age with a diagnosis of type 1 or type 2 diabetes mellitus during the measurement year	**NCQA / NQF/ PQRI/ PCPI**	http://www.ncqa.org/tabid/432/Default.aspx

Part 1: Introduction

Diabetes is a chronic disease that is characterized by a broad range of metabolic abnormalities. Continued medical management and patient self-management are required to prevent acute complications and minimize the risk of complications that develop over time. Although diabetes medical management continues to improve, significant challenges remain. Consider the following:

- Diabetes is a leading cause of disability and death in the United States, affecting an estimated 17 million people – about 6.2 percent of the population. Approximately one-third are unaware of their disease.[1]
- Each year, nearly one million American adults are diagnosed with diabetes.
- Total cost of diabetes in the United States is estimated at more than $98 billion annually.[2]
- HbA1c measures blood glucose control in type 1 and type 2 diabetics. For every 1 percent reduction in results of HbA1c blood tests, the risk of developing eye, kidney, and nerve disease is reduced by 40 percent while the risk of heart attack is reduced by 14 percent.[3] [4]
- Diabetes disproportionately affects racial and ethnic minorities. African Americans, Hispanics, Native Americans, and Asian/Pacific Islanders are more likely to be diagnosed with diabetes. Rates of diabetic-related kidney failure are 2.6 times higher among African Americans. Death rates are also higher among African American, Hispanic, and Native American diabetics.[5]

Although the challenge is daunting, it is clear that experts *do* know what good diabetes care looks like and are continually increasing public knowledge about good diabetes care. The scientific literature, centers of excellence in diabetes care, and the experience of health care organizations are consistent in pointing to common themes in excellent diabetes care.

Performance Measurement: Diabetes HbA1c

It is well accepted that measuring performance allows an organization to document how well care is currently provided and lay the foundation for improvement. The HRSA Core Clinical Measures (CCMs) are a set of performance measures, designed for use by HRSA programs as an integral part of quality improvement programs, to improve care for the safety-net population. More information about the purpose and development of these measures can be found in the **HRSA Core Clinical Measures** module.

The HRSA **Diabetes HbA1c** measure is designed to measure the percentage of patients aged 18 through 75 years with type 1 or type 2 diabetes mellitus that had a most recent hemoglobin A1c (HbA1c) greater than 9 percent. Identifying HbA1c values greater than 9 percent among adult patients aged 18 to75 years allow an organization the opportunity to focus on those patients who are in poor control and at highest risk. Consider the characteristics of a good performance measure and the IOM framework, ***Envisioning the National Healthcare Quality Report***:

- *Relevance*: Does the performance measure relate to a frequently-occurring condition or have a great impact on patients at an organization's facility?
- *Measurability*: Can the performance measure realistically and efficiently be quantified given the facility's finite resources?
- *Accuracy*: Is the performance measure based on accepted guidelines or developed through formal group decision-making methods?
- *Feasibility*: Can the performance rate associated with the performance measure realistically be improved given the limitations of the clinical services and patient population?

To ensure that a performance measure has these characteristics, it is often based on, or aligned with, current evidence-based guidelines and proven measures.

The HRSA CCMs were developed in alignment with national clinical practice guidelines and other performance measures that have been vetted through a national consensus process. The **Diabetes HbA1c** measure aligns with measures endorsed by the National Committee for Quality Assurance (NCQA) and similar performance metrics used by HRSA grantees and programs. The measure also aligns with those adapted by the **Office of Regional Operations (ORO)** and is similar to the one used by the **Bureau of Primary Health Care (BPHC)** in the clinical portion of its **Uniform Data Systems (UDS)** process. Similar measures also exist in the national measure set for **Healthy People 2010**.

HRSA Core Clinical Measure: Diabetes HbA1c

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Diabetes HbA1c	Percentage of patients aged 18 through 75 years with type 1 or type 2 diabetes mellitus who had a most recent hemoglobin A1c (HbA1c) greater than 9 percent	Number of patients from the denominator whose most recent hemoglobin A1c level during the measurement year is greater than 9 percent	Number of patients aged 18 through 75 years of age with a diagnosis of type 1 or type 2 diabetes mellitus during the measurement year	**NCQA / NQF/ PQRI/ PCPI**	http://www.ncqa.org/tabid/432/Default.aspx

As with all performance measures, there are essential inclusions, exclusions, and clarifications that are required to ensure that an organization collects and reports data in the same way. This allows an organization using the measure to compare itself with others. Detailed specifications for the measure, with descriptions of inclusion and exclusion criteria, are found in the section, **Part 3: Data Infrastructure: Diabetes HbA1c**.

Improvement Experience: Diabetes HbA1c

As mentioned above, the **Diabetes HbA1c** measure was chosen to align with existing measures. The data demonstrating the experience with these measures is discussed briefly in this section.

The importance of glycemic control as part of the comprehensive management of diabetes is well documented, and HbA1c testing is a well-established strategy to monitor glycemic control in patients with diabetes. Unfortunately, NCQA data from 2007 reveals that between 13 and 22 percent of patients with diabetes do not get regular HbA1c testing.[6] When tested, significant numbers of patients are in poor control with HbA1c values of 9 percent or greater: 29.6 percent of commercial populations, 27.3 percent for Medicare, and 48.7 percent of Medicaid populations. Systematic approaches are necessary to achieve improvements in the quality of care delivery and health care outcomes for patients.

Putting systems in place to track HbA1c testing frequency and HbA1c values enables an organization to better understand how effectively it is able to care for its patients with diabetes. Identifying adult patients aged 18 through 75 years with HbA1c values greater than 9 percent provides an opportunity for an organization to focus attention and services on those patients who are in poor control and at highest risk. These same tracking systems can facilitate appropriate management and follow-up for patients providing critical steps to help them attain and maintain their established glycemic goals.

Trends in NCQA data revealed organizations that implement best practices to ensure effective, high quality care can result in improved glycemic control for populations of patients. HbA1c testing in commercially insured populations in New Hampshire exceeded 92 percent and testing for Medicaid populations in Minnesota was 88 percent in 2007.[6] Diabetes patients who maintain

near-normal HbA1c values can gain an average extra five years of life, eight years of sight, and six years free from kidney disease. [2]

Part 2: Characteristics for Success: Diabetes HbA1c

Organizations that were successful in improving **Diabetes HbA1c** for patients approached the issue in a systematic way, with careful attention to the factors that have an impact on patients with poor glycemic control. Although clinics may differ in specific workflow, documentation, and staffing models, organizations that experienced successful improvement efforts shared these three fundamental characteristics:

1. Clear direction
2. Functional infrastructure for quality improvement
3. Commitment from leadership

1. Clear Direction

Successful organizations found that it is important to define clearly what they are trying to accomplish. Most often in improvement work, leadership defines an aim that guides an organization's efforts. An aim is a written, measurable, and time-sensitive statement of the accomplishments a team expects to achieve from its improvement efforts. The aim statement contains a general description of the work, the system of focus, and numerical goals. The aim statement includes a very specific indication of what success looks like and may include guidance that further frames the work, including methodologies to be used and budgetary and staffing limitations. Examples of tools used by QI teams to create their aim statements include the **Aim Worksheet** and the **Aim Statement Checklist.**[7] Additional information, including tools and resources to assist an organization in developing its aim statement, can be found in the **Readiness Assessment and Developing Project Aims** module. A completed aim statement for the measure, **Diabetes HbA1c**, is shown in **Example 2.1: Assessing the Aim Statement for Mountain Health Care Organization (MHCO) Using the Aim Statement Checklist.**

The following example provides an aim statement created by the fictional Mountain Health Care Organization's QI team and the checklist the team used to assess its completed aim statement. Using the Aim Statement Checklist to assess the QI team's aim statement provides reassurance that the team included the necessary components of the aim statement for its improvement project.

Example 2.1: Assessing the Aim Statement for Mountain Health Care Organization (MHCO) Using the Aim Statement Checklist

Aim Statement: *Over the next 12 months, we will redesign the care systems of Mountain Health Care Organization to decrease the number of poorly-controlled diabetics in Dr. Billing's practice, so that less than 20 percent of these patients have an HbA1c greater than 9 percent.*

Guidance:

- *No additional staffing will be required as a result of this improvement*
- *A key focus will be systems for patient outreach*

Here is an example of how Mountain Health Care Organization evaluated its aim statement using the Aim Statement Checklist

Aim Statement Checklist for Example 2.1: (7)

- ✓ What is expected to happen?
  MHCO: Fewer patients will have HbA1c of greater than 9 percent indicating poor control
- ✓ Time period to achieve the aim?
  MHCO: 12 months
- ✓ Which system will be improved?
  MHCO: Care systems that improve glycemic control
- ✓ What is the target population?
  MHCO: Diabetic patients in Dr. Billing's practice
- ✓ Specific numerical goals?
  MHCO: Less than 20 percent have a HbA1c of greater than 9 percent (lower is better)
- ✓ Guidance, such as, strategies for the effort and limitations?
  MHCO: As noted, no new staff plus focus on patient outreach

Evaluating what others achieved provides appropriate context for choosing the numerical portion of an organization's aim.[8] While the goal of *zero percent of patients with an HbA1c greater than 9 percent* is optimal, an organization can set an appropriate and realistic goal based on the review of comparable data after consideration of the payer mix of the patient population served.[9] For some measures, it may be possible to find examples of benchmark data, which demonstrates the performance of a best practice. It is important to consider an organization's particular patient population when making comparisons to others' achievements. An organization may consider socioeconomic status and/or race/ethnicity of the population served, organizational size, payer mix, and other criteria in an effort to achieve an accurate comparison. Reviewing what others accomplished may help an organization to understand what is feasible to achieve. The numerical part of the aim should be obtainable, yet high enough to challenge the team to substantially and meaningfully improve. Additional guidance about setting aims can be found in the **Readiness Assessment and Developing Project Aims** module.

When choosing an aim or making performance comparisons for the measure, **Diabetes HbA1c**, the NCQA HEDIS Data Set is one source to consider. Current data is accessible from the **Trending and Benchmarks** section. Of note is the considerable variation among the regions, which correspond to the Health and Human Services Regions of the United States. Sources of data for additional comparisons vary regionally but may include payers, State programs, aggregate HRSA program data, and State or regional quality improvement programs.

2. Functional Infrastructure for Quality Improvement

Successful organizations found that improvement work requires a systematic approach to measuring performance, testing small changes, and tracking the impact of those changes over time. This section describes four essential components of an infrastructure to support quality improvement efforts, including:

- Quality improvement teams
- Tools and resources
- Organizing improvements
- Building on the efforts of others by using changes that worked

There is considerable variation in how this infrastructure is created and maintained. It is important that each component is addressed in a way that fits an organization.

Quality Improvement Teams

Multidisciplinary QI teams are typically tasked to carry out this work. For improvement focused on **Diabetes HbA1c**, it is important to include a provider who wants to focus on decreasing the number of patients with poor glycemic control, i.e., a *provider champion* for improvement.[10] In addition to the provider champion, other appropriate members of a QI team may include:

- Nurses
- Case managers
- Patient outreach specialist
- Patient navigator
- Scheduling staff
- Information specialist
- Other staff involved in the patient care process, such as, receptionists, diabetes educators, administrative staff, medical assistants, pharmacists, and health coaches

It should be noted that patients can add great value to the QI process when prepared to participate in a meaningful way. The reference manual by the National Quality Center (NQC), *A Guide to Consumer Involvement*, has practical ideas to assist an organization on how to involve patients in its QI process.[9]

There are no wrong answers here. Members of a team bring expert knowledge of the work they do for diabetic patients. Together, the team learns where and how its individual actions intersect and how each can have an impact on patients' diabetic care. The ability to think from a systems perspective and the will to improve glycemic control for patients are the primary prerequisites that contribute to a successful improvement team. A more advanced discussion on forming an improvement team can be found in the **Improvement Teams** module.

Tools and Resources

It is important that a QI team have the tools and resources necessary to achieve its established organizational aim. Some personnel may struggle shifting from the daily work of patient care to their roles on the quality improvement team. Those challenges can be straight forward, such as, coordinating meeting times or developing content for the meetings to support the team's quality improvement efforts. Successful QI teams learned that organizing meetings efficiently is essential in their improvement efforts. Tools, such as **Tips for Effective Meetings**, can help a QI team to structure meetings that focus its scheduled time on improvement efforts. Another useful tool includes one that displays data in a way that makes sense to the team members. These types of tools are commonly used by improvement teams to remain focused on the work of improvement. The most important resource needs are uninterrupted time to focus on quality improvement and autonomy to test changes responsibly. Additional team resources and tools can be found in the **Improvement Teams** module.

Organizing Improvements

Successful organizations learned that planning an approach to change is essential. Change is, by nature, unsettling for some and presenting a clear direction and methodology can be reassuring. Most organizations with quality improvement experience adopted methodologies that help them organize their improvements.

As a QI team approaches improvement of patient glycemic control, it should use quality models already embraced by its organization. For example, many organizations adopted the Care Model to organize their approaches to implementing quality improvement changes. Others successfully embraced the FOCUS PDSA approach; both of these models provide a framework for a health care organization to plan and move toward implementing its improvement efforts. There is no *single* model that is considered correct. Organizational alignment of methodology makes sense from the perspective of efficient training. A consistent quality improvement approach and the sharing of improvement ideas among members of a quality team can facilitate the replication of QI activities across an organization and maximize the impact of the overall QI program.

Just as organizations that are experienced in quality improvement activities adopted quality models that guide their work, many embraced a change methodology. A change methodology guides the actual change process, which involves managing *how* changes are made as opposed to *what* changes are made.

For some organizations, all changes are approved by a decision leader and then implemented. Others use a committee structure to evaluate and implement changes. Again, there is no right or wrong methodology, but one change methodology that has been found to be particularly helpful in quality improvement is called the *Model for Improvement*. The Model for Improvement, developed by Associates in Process Improvement, is a simple, yet powerful, tool for accelerating improvement. The model is not meant to replace a change model that an organization may already be using, but rather to accelerate improvement. This model has been used successfully by health care organizations to improve many different health care processes and outcomes.

The Model for Improvement encourages small, rapid-cycle tests of changes. In improvement, this has a distinct advantage in decreasing the time it takes for changes resulting in improvement to be implemented. This methodology also directly involves the individuals who do the work, which provides additional insights into how to rapidly improve care processes.

Building on the Efforts of Others by Using Changes that Worked

One hallmark that successful organizations found beneficial in advancing their quality improvement programs is that everyone across the organization uses the same tools and language to make continuous improvements. A motto of many QI training leaders is "steal shamelessly." This is not the unethical, criminal intent, but instead the sense of "Why reinvent the wheel?" What does it mean to "steal shamelessly"? It means "stealing" or using what has worked in other organizations and "shamelessly" testing and implementing it to create rapid change in one's own organization.

Specific *change ideas* that worked for others to successfully improve glycemic control are detailed later in this module in the **Changes that Work** section. Additionally, an organization that has improvement experience in another measurement area, such as, prenatal care, cancer screening, or immunizations, often adapts the successful tools to use with this measure.

3. Commitment from Leadership

For quality improvement efforts to be effective and sustained, leaders must show commitment to them. Typically, leaders may make a commitment to specific target areas for improvement once they consider the overall needs of the organization, requirements of funders, and how the proposed efforts align with the organization's mission and strategic plan. Leaders that consider quality improvement efforts as an "add-on" may be unable to maintain QI as a priority as other realities compete for the organization's attention and resources. Successful leaders in quality improvement integrate and align QI activities as part of their daily business operations.

A quality improvement team needs to have leadership commitment expressed in a tangible way. Often, it is an explicit dedication of resources, which may include team meeting time, data support, and specific planned opportunities that communicate actionable improvement

suggestions to an organization's leadership. The authority of the improvement team and any constraining parameters should be clear. Detailed information highlighting the important role of leadership in a QI project can be found in the **Quality Improvement** module.

Below is a hypothetical case story that is followed throughout the module and depicts the effort of a fictional QI team as it focuses on improving the number of diabetic patients accessing care in its organization.

The Problem:

Healthy Valley Clinic provides a full range of health services to several communities across a rural area in the southwestern United States. They are staffed by 3.5 FTE providers, 4 medical assistants (MAs) providing 3 FTEs, a part-time nurse, and a full-time receptionist who also functions as the medical records clerk. The clinic serves about 6,000 unduplicated individuals and has a growing prevalence of diabetes in its patient population. Providers dictate notes and maintain paper charts. The clinic recently decided to consider using a free registry system to try to better understand its diabetes care systems. After a particularly challenging week, the providers are very concerned about what seems to be an increasing number of poorly-controlled diabetic patients. They feel the situation is deteriorating and want to understand how to help patients achieve better outcomes.

Part 3: Implementation of HRSA CCM: Diabetes HbA1c

Before following the steps in Part 3, an organization should first make a commitment to decrease the number of poorly-controlled diabetic patients and complete the initial steps outlined in the previous section that include:

- Developing an aim statement
- Creating an infrastructure for improvement
- Gaining commitments from leadership

Performance on this measure indicates how effectively all the steps of the processes used to deliver care work together so that glycemic control is optimized. Because there are so many factors that can have an impact on glycemic control of patients, it helps to visualize how these steps are mapped. The next section defines *Critical Pathway* and illustrates the application of this concept to test improvements to improve the HbA1c in poorly-controlled diabetic patients.

The case story continues…

The Approach:

The organization agreed to focus on improving diabetes care and chose to use the registry it read about in the recent medical literature. The CEO recognized that resources needed to be dedicated to this effort but struggled to allocate them in challenging economic times. He agreed to allocate resources to determine where the organization really was before committing to an improvement initiative. The staff agreed to look further at the diabetic patients of one provider to better inform their decisions. The organization then made several critical decisions:

1. The team decided to focus on the HRSA Core Clinical Measure, **Diabetes HbA1c** to target its highest-risk diabetic patients.
2. It invested resources to evaluate where it was regarding that particular measure and where it wanted to be based on national benchmarks.
3. The team decided to limit this evaluation to the patients of one willing provider, Dr. Harmon.

For baseline information, the team also agreed to allow one part-time MA, who was interested in technology, to take the registry tutorial and learn how to get important information into the registry.

Critical Pathway for Diabetes HbA1c

A critical pathway, also known as a clinical pathway, is a visual depiction of the process steps that result in a particular service or care. The sequence and relationship among the steps are displayed, which reveals a *map* of the care process. Additional information, including tools and resources regarding the mapping of care processes, can be found in the **Redesigning a System of Care to Promote QI** module. In an ideal world, the care process is reflective of evidence-based medical guidelines. Evidence-based medicine aims to apply the best available evidence gained from the scientific method for medical decision making.[11] A map of the care process steps that incorporates all of the known evidence and follows respected evidence-based medical guidelines can be considered the *idealized critical pathway*.

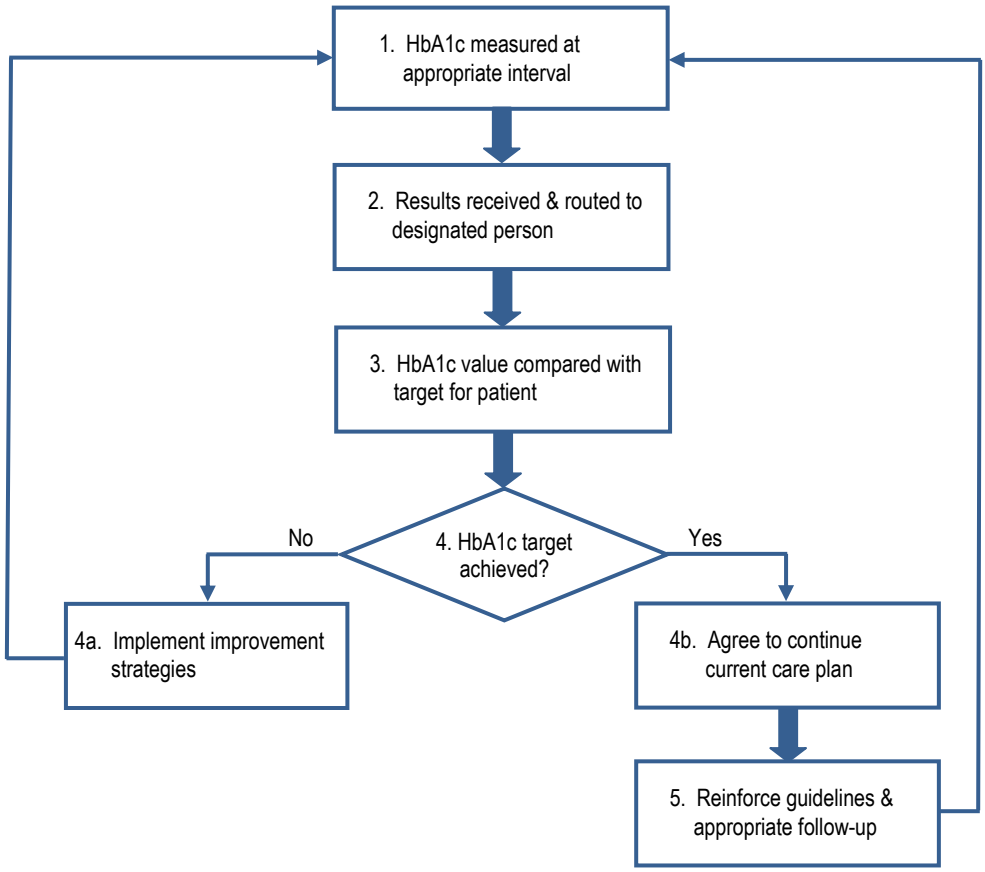
While the needs of individual patients should always be considered, clinical guidelines synthesize the best evidence into a pragmatic set of action steps that strive to provide the optimum health care delivery system. It is important to emphasize that clinical evidence and guidelines will evolve as knowledge progresses; therefore, the idealized critical pathway may evolve over time and not meet the needs of every individual.

Note: Please consider the following regarding critical pathways:

- There can be more than one way to depict the idealized critical pathway.
- Authorities vary on critical issues that have an impact on important decisions in medicine, and there is latitude within guidelines for variation related to less critical matters.
- It is important that an organization agrees on the guidelines with which to align. There are multiple specific guidelines that address processes to optimize mammographic screening for breast cancer. An organization may interpret those guidelines differently than illustrated in Figure 3.1. If so, creation of a different schematic that reflects its interpretation of the best evidence is encouraged. References are located in *Part 6: Supporting Information* at the end of this module.

In **Figure 3.1,** the schematic for **Critical Pathway for Diabetes HbA1c** incorporates available evidence and represents an idealized critical pathway for care to optimize glycemic control. The boxes represent typical steps in care delivery. If these steps happen reliably and well, effective care is delivered.

Figure 3.1: Critical Pathway for Diabetes HbA1c



Walkthrough of the Idealized Critical Pathway

The steps illustrated in the schematic reflect a system that is working well. It is helpful to understand these steps in more detail and how they relate to glycemic control:

1. It is important to know the HbA1c. If an organization follows current clinical guidelines, it needs to ensure that this test is completed (not just ordered) at appropriate intervals depending on the patient's risk.
2. Next, an organization needs to ensure that completed test results are viewed by the correct staff member. In some organizations, all results are routed to the provider. In others, a designated staff member is responsible for reviewing the results as guided by a protocol created by the provider.
3. An organization needs to assess the value of the HbA1c against the goal for the patient. Goals are recommended by clinical guidelines and tailored to the patient's risk and co-morbidity. Regardless of individual variation, a value greater than 9 percent is considered poor glycemic control and is the threshold for the *poor control* measure.

4a. If the value is not what it should be for any given patient, steps must be taken to lower the HbA1c. There are a number of contributing factors that may cause a value to be high. These can be organized into patient-related, care team-related or system-related factors. Individual patient needs should be addressed to drive the HbA1c down. Systematic implementation of improvement strategies in all three areas reduces the HbA1c for individual patients and decreases the percent of the population served with HbA1c greater than 9 percent.

4b. Patient achieves target HbA1c level. Reinforce the care plan to ensure that good glycemic control continues. Any anticipated challenges should be discussed.

5. Interim and follow-up care is then discussed to ensure proper monitoring and that the patient has what is needed to manage his or her care until next seen by the care team. Guidelines are emphasized so the patient understands what screening and examinations are to be done. Appropriate follow-up screening occurs in a timely manner and the cycle repeats.

A quality improvement team benefits from mapping out how care is actually provided. Once it is able to evaluate where there are potential opportunities for improvement, it can use some of the improvement ideas that have worked for others, as outlined in **Table 4.2: Sample Changes That Work**.

A couple of important notes:

- An organization may adopt additional diabetes guidelines that include important care parameters. *The American Diabetes Association Guidelines* and *The American Association of Clinical Endocrinologists/American College of Endocrinology* describe guidelines for comprehensive diabetes care.[12] [13]
- A critical pathway can also be constructed to illustrate ***how care is currently provided*** within an organization (the existing pathway). Understanding the gap between an organization's *existing* critical pathway (how you provide care now), and the *idealized* critical pathway (how to provide reliable, evidence-based care aligned with current guidelines) form the basis for improvement efforts.

Factors That Impact the Critical Pathway

In addition to understanding the steps for providing care for diabetic patients, factors that interfere with optimal care should be understood. As there may be several of these factors, a QI team may find it helpful to focus its attention on factors that interfere with ideal outcomes. This becomes especially useful as plans are developed to mitigate these factors.

Factors that have an impact on **Diabetes HbA1c** can be organized into those that are patient-related, relative to the care team, and a result of the health system. Overlaps exist in these categorizations, but it is useful to consider factors that have an impact on care processes from each perspective to avoid overlooking important ones.

Patient factors are characteristics that patients possess, or have control over, that have an impact on care. Examples of patient factors are age, race, diet, and lifestyle choices. Common patient factors may need to be addressed more systematically, such as, a targeted approach to address

low health literacy, or a systematic approach to educate staff on the cultural norms of a new refugee population. Examples of how patient factors may influence glycemic control include:

- ***Age*** because diabetes is a progressive disease and becomes more challenging to control with age.
- ***Cultural differences*** may affect food choices, affinity for physical exercise, and norms for healthy weight.
- ***Health literacy*** may create barriers in understanding and following a care plan.
- ***Work status*** may create care access issues, or shift work may influence a care plan.
- ***Co-morbid diagnosis*** may complicate treatment choices and the ability to follow a care plan.
- ***Socioeconomic status*** may have an impact on access to medications and food choices.

Care team factors are controlled by the care team. These types of factors may include care processes, workflows, how staff follows procedures, and how effectively the team works together. Care team factors that may influence **Diabetes HbA1c** include the processes and procedures that:

- Staff follows for outreaching to patients to ensure periodic care based on their levels of risk.
- Provide culturally-competent care to address the patients' cultural norms about diabetes care.
- Provide planned, comprehensive care for patients who are seen regardless of their reasons for their visits.

Health system factors are controlled at the *high level* of an organization and often involve financial and operational issues. Health system factors that may influence **Diabetes HbA1c** include:

- ***Cost of care*** such as co-pays and access to affordable medications.
- ***Scheduling systems*** such as the availability of evening and weekend appointments, and wait time may have an impact on access.
- ***Location*** such as unavailable transportation or unsafe location may present barriers to keeping appointments.

These factors, when added to the critical pathway, create another dimension to the map as shown in **Figure 3.2**:

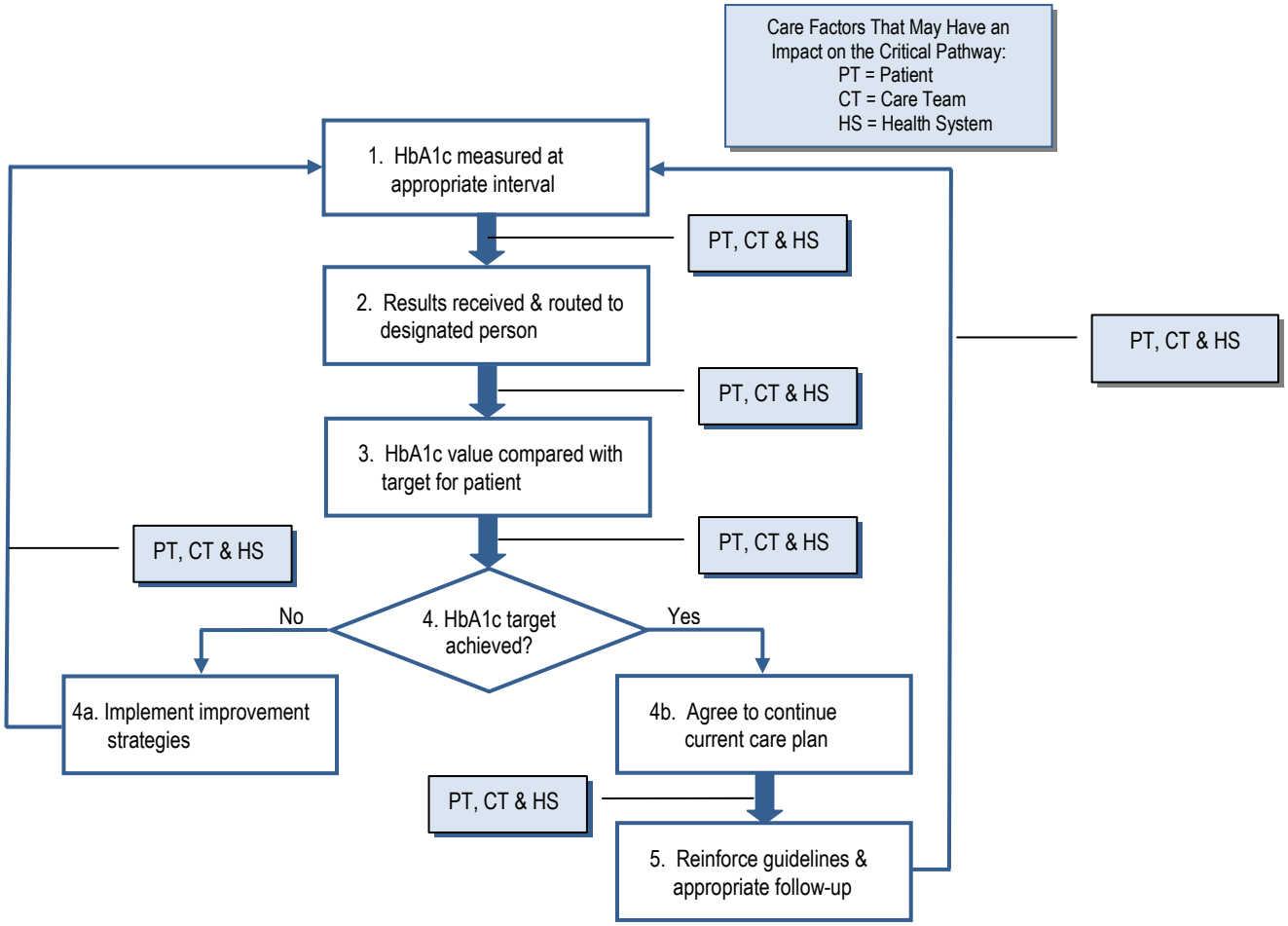
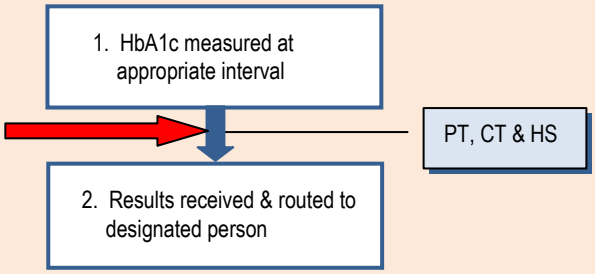


Figure 3.2: Care Factors That Have an Impact on the Critical Pathway for Diabetes HbA1c

Next, a team may identify specific factors that pertain to the way care is provided for its patients. The team may look at Step 1: *HbA1c measured at appropriate interval*, and Step 2: *Results received and routed to the designated person* of the critical pathway. What factors have an impact on how effectively, timely, and reliably Step 2 follows Step 1? It is tempting to consider the first thoughts that come to mind, but teams are best served by systematically thinking through the potential impact of each category. **Example 3.1** illustrates a team's output:

Example 3.1: A Team's Brainstorming Session



The team did some quick checking and found that HbA1c tests were ordered appropriately but patient follow-through was erratic. Once the test was done, the results were reliably transmitted electronically and given directly to the provider of record. Using this information, the team brainstorms on factors that would likely have an impact on the arrow (or opportunity) between Steps 1 and 2 of the critical pathway for **Diabetes –HbA1c**.

Factor Category	**Factors pertinent to our organization – Steps 1 and 2**
Patient	Patients do not have a clear understanding of the disease and the importance of regularly monitoring their HbA1c levels; patients experience transportation issues
Care Team	No staff, workflows, or prompts dedicated to HbA1c testing frequency; available educational materials are not culturally appropriate for the population; no provider consensus about how frequently to test HbA1c
Health Systems	Patients needed to have test done at another location and required an additional co-pay; *no news is good news* policy about lab results

The team continues to look at different parts of the pathway to identify relevant impacts for each part. Once it is able to evaluate where there are potential opportunities for improvement, it can use this information to target its efforts. Additional examples of strategies to improve care for the measure, **Diabetes HbA1c,** are described in **Part 4: Improvement Strategies** of this module.

Once the team visualizes the pathway and identifies opportunities for improved care, the next step is to collect and track data to test and document them. First, a QI team needs to determine *how* to collect data to support its improvement work. This step is essential for understanding the performance of its current care processes, before improvements are applied, and then monitoring its performance over time.

Data Infrastructure: Diabetes HbA1c

This section begins to address the critical role of data throughout the improvement process. It is important to recognize that different types of data are collected during the improvement project. First, data to calculate and monitor the **Diabetes HbA1c** performance measure results is needed. Monitoring a performance measure involves calculating the measure over time and is used to track progress toward a numerical aim. This section provides an overview of what is needed. A detailed and stepwise approach follows to explain the types of infrastructure elements needed to gather data to support improvement. Second, changes an organization makes to improve care processes and their effects must be tracked. Tracking the impact of changes reassures the team that the changes caused their intended effects.

Data Infrastructure to Monitor the Performance Measure—An Overview

There are three major purposes for maintaining a data infrastructure for quality improvement work:

- To know the starting baseline
- To track and monitor performance as changes are implemented
- To perform systematic analysis and interpretation of data in preparation for action

The first step to creating a data infrastructure for monitoring the performance measure is to determine the baseline. A baseline is the calculation of a measure before a quality improvement project is initiated. It is later used as the basis for comparison as changes are made throughout the improvement process. For the **Diabetes HbA1c** measure, an organization can determine the percentage of patients with an HbA1c value greater than 9 percent. Performance reflects the current organizational infrastructure and the patient's interactions with existing care processes and the care team.

Baseline data is compared to subsequent data calculated similarly to monitor the impact of quality improvement efforts. The details of how to calculate the data must be determined to ensure that the calculation is accurate and reproducible. The difference between how an organization provides care now (baseline) and how it wants to provide care (aim) is the gap that must be closed by the improvement work.

The next step of data infrastructure development involves a process in place to calculate the measure over time as improvements are tested. A QI team's work is to make changes, and it is prudent to monitor that those changes result in achieving the stated aim. This involves deciding how often to calculate the measure and adhering to the calculation methodology.

Finally, an organization's data infrastructure must include systematic processes that allow analysis, interpretation, and action on the data collected. Knowledge of performance is insufficient for improvement. It is important for an organization to understand why performance is measured and to predict which changes will decrease the number of poorly-controlled diabetics based on an organization's specific situation. Collecting data related to specific changes and overall progress related to achieving an organization's specified aim are important

to improvement work. The next section describes in more detail how to develop a data infrastructure to support improvement.

Implementation: Diabetes HbA1c

This section explores each step to create the data infrastructure used to improve performance on the measure, **Diabetes HbA1c**.

Note: If an organization is currently funded by HRSA, some performance measures, including the HRSA CCM set, may be among those that will be reported to HRSA. An organization should consult its program's Web site plus links to bureau- and office-required guidelines and measures for more information:

BPHC MCHB HAB BHPr ORHP OPAE/OHITQ ORO

General information on HRSA grants, including searchable guidelines, is available and accessible at the **HRSA Grants Web site.**

Grantees are encouraged to contact their project officers with questions regarding program requirements.

1. Step 1 - Determine and Evaluate the Baseline

As discussed above, a *baseline for improvement* is a calculation that provides a snapshot of the performance of the *systems* of care for a measure before improvements are applied. The baseline is determined by calculating the measure and collecting the information for the numerator and denominator.

Determination of a baseline is accomplished by actually calculating the measure and requires that the information for the numerator and denominator be collected. There are several methods to collect this information. While established electronic methods are more efficient, manual chart audits using random sampling techniques are equally valid.

Consistent data collection sources and methodologies are critical to ensure reliable data. Please note that the tables referenced in this section are from the *NQF-Endorsed National Voluntary Consensus Standards for Physician-Focused Ambulatory Care Appendix A-NCQA Measure Technical Specifications* (April, 2008 V.7. Pages 20-23 and 26-28). The methodologies suggested are also from NQF and can be found here.

The following tables and figure depict a decision algorithm for the measure, **Diabetes HbA1c**. The algorithm outlines the steps an organization follows to determine its baseline and monitor improvements for **Diabetes HbA1c**:

Identify the Denominator	
The denominator for this measure is the number of patients aged 18 through 75 years of age with a diagnosis of type 1 or type 2 diabetes mellitus during the measurement year	
a. Use a one-year date range, hereafter called the measurement year.	
b. Choose a selection method	Pharmacy method—patients who were dispensed insulin or oral hypoglycemics/ antihyperglycemics during the measurement year or year prior to the measurement year on an ambulatory basis.
	Do not include patients who take metformin in the denominator without another reason to do so. Metformin is used for other conditions as well as to treat diabetes.
	Claim/Encounter Data—patients who had two face-to-face encounters with a diagnosis of diabetes on a different date of service
c. Exclude those who have a diagnosis of polycystic ovaries, steroid induced diabetes, or gestational diabetes but do NOT have a diagnosis of diabetes from the denominator	Exclude patients where the HbA1c value is suspected to be inaccurate. The value of HbA1c needs to be considered in the context of the patient as the assay is not foolproof. Depending on the assay method being used, certain hemoglobinopathies may interfere with results. This problem is highly method-dependent. Inaccurate results may be obtained in the presence of salicylates, chronic alcohol or opiate use, hyperbilirubinemia, liver or renal disease, iron deficiency, vitamin C, vitamin E, hypertriglyceridemia, lead poisoning, and when there are conditions of abnormal red blood cell turnover such as in anemia.

Identify the Numerator
a. Based on an organization's systems, evaluate all of the individuals who remain in the denominator and choose an Electronic Method or the Medical Record Audit method to determine the numerator. For Electronic Method, use electronic data from an Electronic Medical Record or registry to identify the most recent HbA1c test during the measurement year. The patient should be included in the numerator if the:
i. Result of the HbA1c is greater than 9 percent
ii. Most recent test result is missing (*even if documentation of test ordered exists*)
iii. HbA1c test was not done during the measurement year
b. Medical Record Audit: Audit all patients in the denominator or use valid sampling methodology. The records audited may be electronic or paper. Include the patient in the numerator if the:
i. Result of the HbA1c is greater than 9 percent
ii. Most recent test is missing (*even if documentation of test ordered exists*)
iii. HbA1c test was not done during the measurement year

Calculate the Measure
Divide the numerator by the denominator and multiply by 100 to get the percentage of the diabetic population with poorly-controlled HbA1c. ***Note: This percentage also includes those whose test results are unknown or not done within the measurement year, both of which require attention in order to improve diabetes management and outcomes***.

NQF-Endorsed™ National Voluntary Consensus Standards for Physician-Focused Ambulatory Care
APPENDIX A –NCQA Measure Technical Specifications
April, 2008 V.7

DIABETES

HbA1c Management: Testing (Source: NCQA/Alliance)

DESCRIPTION: The percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had:

- Hemoglobin A1c (HbA1c) testing

NOTE:

- *There may be a high rate of false positives when using laboratory data to identify diabetics because diabetes Diagnosis codes are frequently reported on laboratory tests used to rule out diabetes; therefore, laboratory data may not be used to identify diabetics. Using the codes provided in the scope of this measure ensures that laboratory data is not used to identify diabetics.*

NUMERATOR	DENOMINATOR	EXCLUSION	CODES	DATA SOURCE
ELECTRONIC SPECIFICATION: An HbA1c test performed during the measurement year, as identified by claim/ encounter or automated laboratory data. Use any code listed in Table CDC-D. MEDICAL RECORD SPECIFICATION: One or more HbA1c tests performed during the measurement year. At a minimum, documentation in the medical record must include a note indicating the date on which the HbA1c test was performed and the result. Notation of the following in the medical record may be counted: • A1c • HbA1c • Hemoglobin A1c	ELECTRONIC SPECIFICATION: Patients 18-75 years of age as of December 31 of the measurement year who had a diagnosis of diabetes (type 1 or type 2). Two methods are provided to identify patients with diabetes during the measurement year, or the year prior to the measurement year: pharmacy and claim/encounter data. *Pharmacy data:* Patients who were dispensed insulin or oral hypoglycemics/ antihyperglycemics during the measurement year or year prior to the measurement year on an ambulatory basis (Table CDC-A).	Exclude patients with a diagnosis of polycystic ovaries (Table CDC-O) who did not have any face-to-face encounters with a diagnosis of diabetes, in any setting, during the measurement year or year prior to the measurement year. Diagnosis of polycystic ovaries can occur at any time in the patient's history, but must have occurred by December 31 of the measurement year. Exclude patients	Table CDC-A: Prescriptions to Identify Diabetics Description / Prescription Alpha-glucosidase inhibitors: • acarbose • miglitol Antidiabetic combinations: • glimepiride-pioglitazone • glimepiride-rosiglitazone • glipizide-metformin • metformin-pioglitazone • metformin-rosiglitazone • metformin-sitagliptin Insulin: • insulin aspart • insulin aspart-insulin aspart protamine • insulin detemir • insulin glargine • insulin glulisine • insulin inhalation • insulin isophane beef-pork • insulin isophane human • insulin isophane pork • insulin isophane-insulin regular • insulin lispro • insulin lispro-insulin lispro protamine • insulin regular beef-pork • insulin regular pork • insulin zinc beef-pork • insulin zinc extended human • insulin zinc human • insulin zinc pork Meglitinides: • nateglinide • repaglinide Miscellaneous antidiabetic agents: • exenatide • pramlintide • sitagliptin Sulfonylureas: • acetohexamide • chlorpropamide • glimepiride • glipizide • glyburide • tolazamide • tolbutamide Thiazolidinediones: • pioglitazone • rosiglitazone • troglitazone	Patient demographics, claims or encounter data for visits, procedures and pharmacy. The medical record option requires manual or electronically coded data for visits or encounters to determine the sample, and access to either written or electronic medical records to both confirm information in the sampling

Page 20 of 111

Compare an organization's performance to national benchmarks and other available data. The NCQA Web site updates national and State performance on this measure on an annual basis. Note that there is considerable variation among reported practices. Other opportunities for comparison data are from payers, State diabetes control programs, State and regional quality improvement organizations, as well as aggregate reports for specific HRSA-funded programs.

Decide if the performance is satisfactory based on available data from reliable sources. It is important to consider the organizational capacity and constraints, but it is recommended that an organization's aim is high. An organization with a low performance may want to allow a longer time to achieve excellence, but striving to reach an HbA1c value less than 9 percent is feasible for most. If the performance is satisfactory, an organization may wish to choose another measure and focus on other systems of care.

Note: If an organization is currently funded by HRSA, some performance measures, including the HRSA CCM set, may be among those that will be reported to HRSA. An organization should consult its program's Web site plus links to bureau- and office-required guidelines and measures for more information:

BPHC MCHB HAB BHPr ORHP OPAE/OHITQ ORO

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Grantees are encouraged to contact their project officers with questions regarding program requirements.

If the performance is unsatisfactory, consider adopting the measure and using it to monitor improvements to the care delivery system. An organization should understand if a measure is adopted for improvement, ongoing and regular measurement is necessary to reach and sustain its organizational goals. More information regarding measurement can be found in the **Managing Data for Performance Improvement** module.

Note: Detailed specifications, including instructions to identify the denominator and numerator for the measure, **Breast Cancer Screening**, can be accessed on the **HRSA Clinical Quality Performance Measures** Web site.

Evaluate the baseline. Initially, a team compares its baseline to the performance it hopes to achieve. It is important to remember this gap in performance is defined as the difference between how the care processes work now (baseline) and how an organization wants them to work (aim). An organization may often modify its aim or timeline after analyzing its baseline measurement and considering the patient population and organizational constraints.

As an organization moves forward, the baseline is used to monitor and compare improvements in care over time. While it is important for an organization to stay focused on its aim, it is equally significant to periodically celebrate the interim successes.

2. **Step 2 - Create a reliable way to monitor performance over time as improvements are tested. An organization should:**

Standardize its processes and workflows to ensure the team collects and calculates performance data the same way over time. An organization should document exactly how the data is captured so staff turnover does not interfere with the methodology:

a. Determine the frequency performance is calculated. Frequent data collection is often associated with higher levels of improvement. Monthly measurement is recommended, if feasible, as it is associated with a higher level of team engagement

and success. If monthly is infeasible, quarterly measurements may be obtained. Less frequent performance measurements are adequate for reporting purposes, but not for supporting improvement efforts. An advanced discussion can be found in the **Managing Data for Performance Improvement** module.

b. Chart and display results. A simple chart audit form is appropriate for manual audits and can be repeated frequently as desired. Results of multiple audits can be presented in a graphic format to demonstrate trends.

Note: The frequency of team meetings is not necessarily prescribed for success. Many successful teams meet once a week while others may meet bi-weekly when focusing their improvement efforts on any given measure. Success of these meetings is rather the output of the team members' active engagement in the meeting and being prepared to report on recent improvement findings. More information, including resources and tools supporting developing and implementing effective team meetings can be found in the **Improvement Teams** module.

3. Step 3 - Create systematic processes that allow an organization to analyze, interpret, and act on the data collected.

Having the data is not enough. Improvement work involves thinking about the data and deciding what to do as a result of that analysis. A QI team needs to put processes in place – team meetings, scheduled reports, and periodic meetings with senior leaders, to use the data tracked. This section describes how a QI team may accomplish the work of creating actionable plans based on the data collected. In **Example 3.2**: **QI at Team Excelsior Health,** the hypothetical scenario illustrates how a team may use these concepts to act on its data:

a. **Analyze: What are the data trends?** Tracking performance over time for the measure, **Diabetes HbA1c,** is critical to successful improvement, but calculation of performance is not enough. It is important for a team to meet to analyze the data on a regular basis. QI teams that are experienced in looking at data recognize these common patterns:

- Performance is improving
- Performance is decreasing
- Performance is flat
- Performance has no recognizable pattern

Additional examples of common data patterns are provided with further explanation in the **Managing Data for Performance Improvement** module**.** It is typical for a team to see little movement in its data over the first several months. If a team has chosen to monitor an associated process measure, such as, the percent of no-show diabetic patients who are rescheduled, performance improvement may be evident more quickly. Regardless, it is important that a QI team review performance progress regularly. A QI team that meets regularly and calculates performance monthly should spend part of one meeting each month reviewing its progress to date.

b. **Interpret: What do these data trends mean?** A QI team needs to then interpret what these data trends mean within the context of its own organization. If performance is increasing, but has not yet reached the numerical aim, perhaps the changes in place are having the desired effect and the aim will be reached over time. If performance is decreasing, what has changed? Are there new care process changes, a failure of registry data input, or a large increase in those patients included in the registry? If performance is flat, did the organization maximize the benefits from changes implemented or was there some regression to the former way of doing things? Improvement trends that have reached a plateau may indicate that an organization needs to think differently about future changes. A few suggestions that an organization may consider when experiencing a plateau in improving are listed below:

   i. Consider looking at outliers to determine barriers to patient access to care for diabetes, for example, lack of insurance, transportation, or language and cultural differences.

   ii. Consider changes in a different part of the framework to get improvement back on track. If using a critical pathway approach, an organization may look at the steps prior to where the problem seems to be. If a Care Model approach is used and the team worked hard on delivery system design issues, opportunities to better leverage the clinical information systems or engage the community may be considered.

   Interpretation of data over time is critical in determining where a team will target its efforts. Additional tools that can assist a team in understanding underlying causes for data trends are beyond the scope of this manual but are discussed in detail in a monograph that was published by the NQC, **A Modern Paradigm for Improving Healthcare Quality**.

c. **Act: Make decisions based on data**. Once a QI team has a better understanding of what the data means, efforts should be targeted to further advance the performance toward the aim. Often the decisions are made at the team level about what to tackle first. Then small tests of change can be accomplished to determine what improvements could be implemented to enhance performance. The practice of using small tests of change actually allows multiple changes to be tested simultaneously.

Note: An advanced discussion on how to use the data collected to advance an organization's improvement, including resources and tools to support improvement, can be found in the **Managing Data for Performance Improvement** module.

Example 3.2: QI Team at Excelsior Health

The Quality Improvement (QI) Team at Excelsior Health worked diligently to improve HbA1c levels for its diabetic patients over the last several months. The team focused on patient education, following testing guidelines, and streamlined those processes. But during the last three months, the performance remained the same at 30 percent, which was below its aim of having less than 20 percent of its patients with an HbA1c greater than 9 percent.

Example 3.2: QI Team at Excelsior Health

Analysis: The team noted improvement initially. Registry input, care processes, and patient volumes seemed to be stable but performance was flat for the last three months.

The team leader asked for a list of those patients who had an HbA1c ordered but did not have the test completed–outliers for the measure. Further study of these specific cases found that over half of those patients were uninsured.

Interpretation: Because there was initial improvement followed by several months of flat performance, the team leader looked for obvious changes in processes that would have an impact on performance, but found none. The team leader interpreted the data to mean that initial changes provided some improvement, but not enough to achieve its aim and have the desired impact. More work was needed. The team leader employed a common strategy to find additional opportunities; i.e. he looked at the population not in compliance (the outliers) for a common cause to be addressed. In this case, a common thread was that patients were coming in for care but were not able to follow through with testing.

This information allowed the team to consider ways to assist uninsured patients with following through on lab testing. They looked at *Sample Changes that Worked* (Table 4.2) for ideas then added suggestions based on its own patient population. The team decided to increase focus on access to testing. A proposal was submitted to the organization leadership to purchase a machine that would allow it to perform HbA1c testing in the health center. A cost analysis was done that included cost of the machine, materials and staff training, as well as potential revenue. The purchase was approved and systems designed for implementing its use. The improvement team will continue to monitor its performance to determine if this change contributes to achieving its aim statement goals.

Act: The information gathered from the analysis and interpretation of the data allowed the team to focus its next efforts. Since numerous patients were not following through with testing, the team targeted its efforts on improving access to affordable testing. This enabled the team to focus on PDSAs to test changes specific to these areas and monitor its progress.

A QI team leader needs to monitor the pace of the progress over time. If there is insufficient progress to meet the specified aim, reasons should be analyzed and addressed. One organization may choose to accelerate its improvement efforts; another may decide to extend its initial allotment of time to achieve its aim and consider other constraints within the organization.

Part 4: Improvement Strategies: Diabetes HbA1c

The actual improvement process is composed of three steps that respond to the following questions:

1. What changes can an organization make?
2. How can an organization make those changes?
3. How can an organization know the changes caused an improvement?

What Changes Can an Organization Make?

It is important to understand that improvement requires change, but not all change results in improvement. Considering all of the possible changes that can be made to health care systems, significant effort has been dedicated to creating various quality improvement strategies providing a framework that organizes possible changes into logical categories. Frameworks for change in

health care quality improvement are known as *quality models* and have been tested to guide change. In fact, because there may be limited resources to dedicate to improvement, most organizations adopt one or more quality models to guide their improvement efforts. There is not a right or wrong approach, and there are many areas of overlap in quality models. Experienced quality improvement teams often use multiple strategies to overcome challenges as they progress. Two approaches often used by teams that are working to improve performance on **Diabetes HbA1** care are the Care Model approach and the *Critical Pathway* approach.

The case story continues...

The Improvement Journey:

Over the next several weeks, the registry was populated with data from Dr. Harmon's patients. Using the parameters specified for the measure's numerator and denominator, performance was calculated as 49 percent of patients without a timely HbA1c or a value of greater than 9 percent. Although Dr. Harmon knew things were not good, he was surprised by the results and did not believe the data. Because there was such a gap in performance and its goal, the organization decided on a formal effort. It took the following steps:

1. Received the support of leadership. Dr. Harmon requested that all clinical staff be involved, but the CEO felt that they could not afford that level of resource support. They negotiated a two-hour kickoff meeting and a one-hour meeting each week for up to three staff members. They decided that only Dr. Harmon would actively participate from the provider staff and that the project would initially focus on his patients only. In addition, the MA would continue to have a few additional hours each week to keep the registry up to date and run monthly progress reports. Although active participation was limited to one provider, everyone would be kept up to date during monthly staff meetings.
2. A Diabetes Improvement Team was formed. Dr. Harmon played a clinical leadership role and the MA, who functioned both as an MA and the registry expert, was invited to attend. The receptionist had a strong family history of diabetes and was anxious to participate. The dietician from the neighboring hospital was invited to participate in the team meeting twice a month. The receptionist agreed to keep track of all documentation related to the project and to ensure the meetings stayed on track. The MA agreed to monitor the time and to provide insights into her role on the care team as well as data. Dr. Harmon agreed to provide clinical leadership and also to provide or facilitate any training that would benefit the team.
3. The team developed the following aim statement: *We will improve the care provided to Dr. Harmon's patients so that in 12 months, less than 25 percent of his patients will have an HbA1c greater than 9 percent.*
4. The team agreed to try out strategies to make sure the MA received all data collected at the time of the visit for data entry. They also decided to look at the previous month's data during its team meeting on the second Thursday of each month.
5. The focus was on what it could do to improve diabetes care and to do it as quickly as possible. The team chose the critical pathway improvement strategy.

1. **Care Model Approach:** Implementing the changes described in the Care Model is a proven method to improve care delivery. The Care Model is an organizational framework for change and is organized into six domains:
    a. Organization of Health Care
    b. Clinical Information Systems
    c. Delivery System Design
    d. Decision Support
    e. Community
    f. Self-Management Support

Changes within these domains can effectively leverage transformation of a current reactive care system to one that better supports care for chronic disease conditions, such as diabetes. Changes within these domains can effectively leverage transformation of a current reactive care system to one that better supports proactive care. If an organization does not have general experience with this model, reading information on the Care Model Web site before proceeding is recommended. The Care Model recognizes that care for diabetes is ongoing and requires more proactive care than the health care system often provides. This model is implemented to improve care by working in six domains, defined below, that transform the way care is delivered:

Community—To improve the health of the population, a health care organization reaches out to form powerful alliances and partnerships with State programs, local agencies, schools, faith organizations, businesses, and clubs.

Organization of Health Care—A health care system can create an environment in which organized efforts to improve the care of people with chronic illness take hold and flourish.

Self Management—Effective self management is very different from telling patients what to do. Patients have a central role in determining their care and one that fosters a sense of responsibility for their own health.

Delivery System Design—Delivery of patient care requires not only to determine what care is needed, but to clarify roles and tasks to ensure the patient receives the care; that all of the clinicians, who take care of a patient, have centralized, up-to-date information about the patient's status, and make follow-up a part of their standard procedures.

Decision Support—Treatment decisions need to be based on explicit, proven guidelines supported by at least one defining study. A health care organization integrates explicit, proven guidelines into the day-to-day practice of primary care providers in an accessible and easy-to-use manner.

Clinical Information System—A registry, that is, an information system that can track individual patients and populations of patients, is a necessity when managing chronic illness or preventive care.

Definitions above adapted from the Institute for Healthcare Improvement Web site.[14]

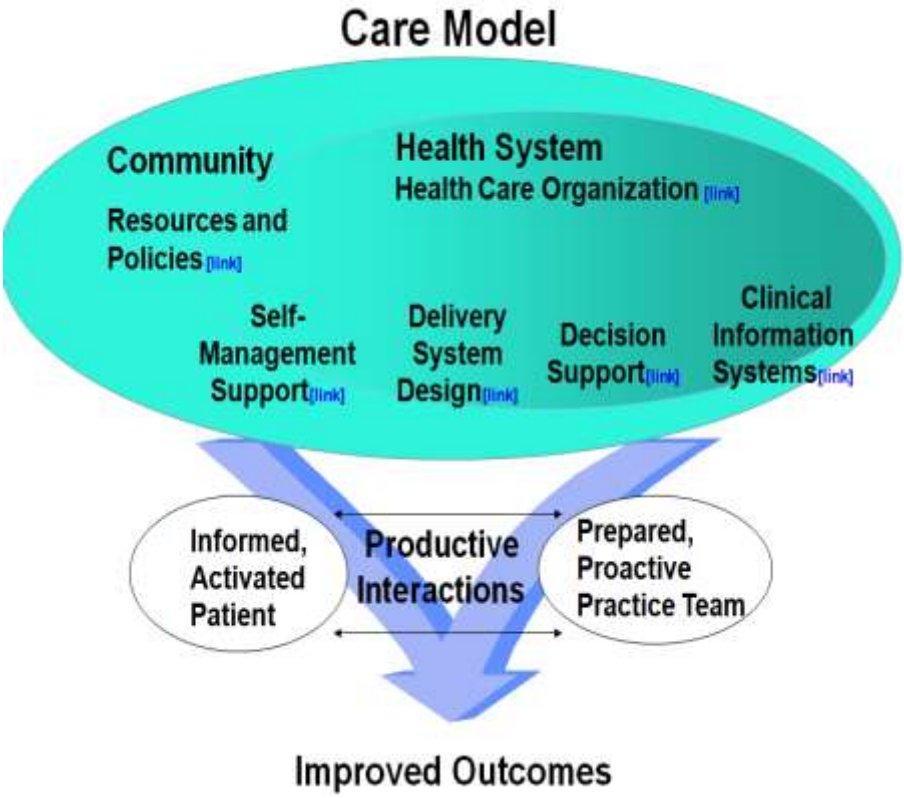


Figure 4.1: The Care Model

In **Table 4.1: Care Model Key Changes**, key changes are presented that have been used successfully to improve diabetes care within the Care Model framework.

Table 4.1: Care Model Key Changes

Community	Organization of Health Care	Self Management	Delivery System Design	Decision Support	Clinical Information System
Establish linkages with organizations to develop support programs and policies for patients with diabetes	Make improving chronic care a part of the organization's vision, mission, goals, performance improvement and business plan	Use diabetes self-management tools that are based on evidence of effectiveness	Use the registry to review care and plan visits for all diabetics, regardless of reason for visit	Embed evidence-based guidelines in the care delivery system	Establish an EMR with registry functions or stand alone registry to track key diabetes outcomes
Link to community resources for defrayed medication costs, education, and materials	Make sure senior leaders and staff visibly support and promote efforts to improve chronic care	Set and document self-management goals with patients	Assign roles, duties, and tasks for planned visits to a multidisciplinary care team. Use cross-training to expand staff capability.	Establish linkages with key specialists to ensure that primary care providers have access to expert support	Develop processes for use of the registry, including designating personnel for data entry, assuring data integrity, and registry maintenance
Encourage participation in community education classes and support groups	Make sure senior leaders actively support the improvement effort by removing barriers and providing necessary resource	Train providers and other key staff to help patients with self-management goals	Use planned visits in individual and group settings	Provide skill-oriented interactive training programs for all staff in support of chronic illness improvement	Use the registry to generate reminders and care-planning tools for individual patients
Raise community awareness through networking, outreach, and education	Assign day-to-day leadership for continued clinical improvement	Follow up and monitor self-management goals Use group visits to support self management	Make designated staff responsible for follow-up by various methods, including outreach workers, telephone calls, and home visits	Educate patients about guidelines	Use the registry to provide feedback to care team and leaders

This toolkit is meant as a guide to help organize ideas, but is also designed to allow flexibility for creative planning.

Note: An organization may choose to adapt and refine a tool to assist improvement for the measure, **Diabetes HbA1c**. Testing the measure before fully implementing it offers a way to try something new and modify it before additional resources are spent.

The case story continues...

The QI Team:

The initial meeting was the launch meeting and time was spent looking at the baseline data, understanding the critical pathway for glycemic control, and reviewing the model for improvement change methodology. The team was asked to observe the systems currently in place regarding diabetes care and be prepared to discuss them the following week. The team also asked the MA to organize a chart audit with the nurse to look at those patients who did not have a timely value for HbA1c.

At the second meeting the team mapped out challenges it observed to its current system of care and reviewed the results of the chart audit. Common themes were:

- Of eight diabetic patients on Dr. Harmon's schedule, two did not arrive for their appointments. They

realized there was no clear follow up of "no shows" after one attempt.

- Of three patients due for HbA1c, two were referred for the test. The one not referred was a patient who already had so many things to discuss that the lab order was overlooked.
- Of the two patients who were returning to discuss results, one completed the test and the other had car trouble and did not appear. He had also missed his follow-up appointment, so it was now well over six weeks after his test was due.
- The eighth patient came in for a sore knee. Although she had diabetes, the visit was focused entirely on the knee pain and the HbA1c was overlooked.
- The chart audit was helpful. The lab slip from those patients drawn in the hospital lab now came back as a full page report that was filed in the lab section. The other primary lab reported back in a half sheet. These were placed by protocol along with all of the other labs that were filed as half sheets, attached two slips to a page to save space in the chart. As a result, some of the labs that were completed were missed. Also, some patients moved or transferred care and had not been purged from the practice management system so were counted when they should not have been.

2. **Critical Pathway Approach:** As with all critical pathways, good performance relies on many different systems and processes working together efficiently. An organization is encouraged to map its own critical pathway for **diabetes care - glycemic control**, or refer to the schematic in **Figure 4.2**. Often when a QI team maps its pathways, it readily can see how complex each step is. It is common for different team members to do the same step differently. Workflow inefficiencies become clear when an organization visualizes how each step is completed and the interdependencies among the steps. Some teams are overwhelmed by the possibilities of changes that can be made in their systems; others focus only on a specific group of factors.

   One way to organize the factors that have an impact on the systems is to consider that some are controlled by the patient, others are primarily controlled by the care team, and still others are inherent in the system of care delivery. All three sets of changes must be considered to improve systems of care. In general, these categories can be defined as follows:

   - **Patient changes—**efforts to support self-management efforts, patient engagement, and navigation of the care system
   - **Care team changes—**changes in job duties or workflow that assist to retain patients in care and ensure timely evidence-based diabetes care
   - **Health system changes—**changes that have an impact on how care is delivered, independent of who delivers it

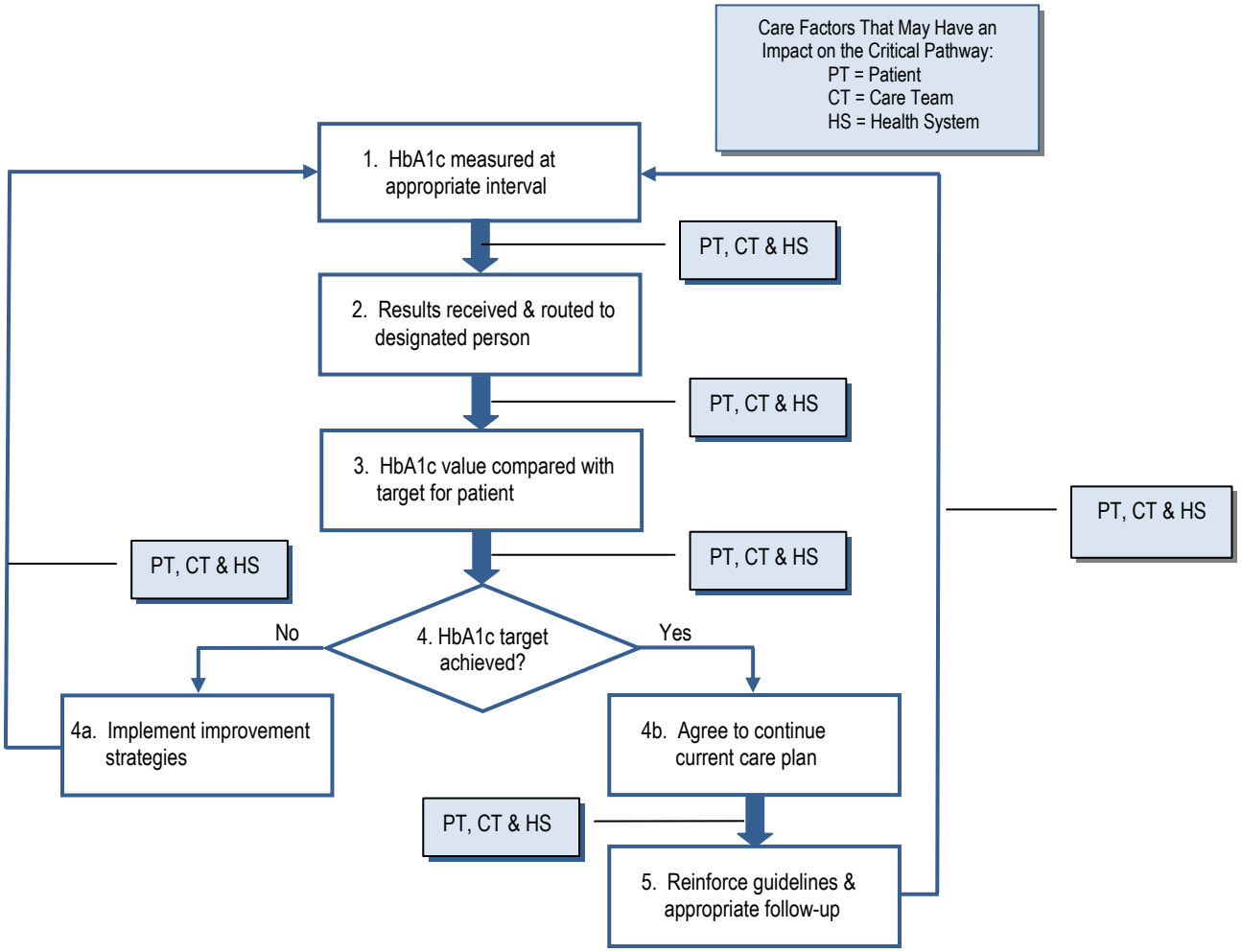


Figure 4.2: Critical Pathway Approach

A team should use the steps along the critical pathway to target improvements. For this measure, **Diabetes HbA1c,** influences on performance begin by ensuring that HbA1c is measured at the appropriate time interval (not simply ordered), as indicated by the first step in the critical pathway, ***HbA1c measured at appropriate interval.***

An organization should ensure that patients are appropriately educated regarding the importance of regularly testing HbA1c values based on their level of risk. Providing education to patients also affords an organization the opportunity to assess patient barriers to testing, such as, lack of insurance or cost. Successful organizations have often aligned resources in the community for testing HbA1c at a reduced cost for patients creating a true partnership in patient care.

An organization can think through each part of the critical pathway in turn, teasing out what happens and what could be improved. In **Table 4.2**, changes that have worked for other QI teams are matched with the part of the system on which they have the most

impact. These ideas are not meant to be inclusive, but to start a dialogue of what may improve each part of the critical pathway in an organization, and thus improve it overall.

Changes That Work

Table 4.2: *Sample* Changes That Work That Are Linked to the Critical Pathway for Diabetes HbA1c

Table 4.2: *Sample* Changes That Work That Are Aligned with the Critical Pathway for Diabetes HbA1C in Figure 4.2

Number/Area of Critical Pathway		Patient Changes	Care Team Changes	Health System Changes
1	Changes that have an impact on timely measurement of HbA1c	• Educate patients with educational resources regarding the importance of routine HbA1c tests • Assess barriers to HbA1c testing; address barriers in partnership with patients	• Designate care team member to outreach to patients due for HbA1c • Ensure messaging from the care team regarding importance of periodic HbA1c • Ensure HbA1c is ordered when it is due, regardless of reason for visit	• Prompts for HbA1c due at point of care – registry and flow sheets • Implement standing orders for HbA1c per protocol • Consider on-site HbA1c measurement - may correlate with higher rate of testing
2	Assuming the A1C has been measured, ensure the results are viewed by someone who can make a decision about whether the value is above, below, or at target		• Referral information is clear about how the results will be communicated to the practice • Clear procedures for how HbA1c results are routed once received – usually to a provider or another health professional who can act on the results by protocol	• Lab tracking systems that prompt if results not logged as expected • Prompts for the HbA1c are not turned off when test ordered, but rather when results received
3	Results need to be acted upon using clinical guidelines in context of other issues specific to the patient	Use shared decision making with patients to agree on target values for patients considering guidelines, co-morbidities, and patient preferences	• Ensure outreach to patient with lab test results and achieving targets per guidelines; *no news is good news* strategy for notifying patients about lab tests is not aligned with good care • Providers should agree on guidelines so that care among providers is congruent • Providers have continuing educational opportunities to stay current with appropriate recommendations • Improve continuity; continuity typically improves patient trust in making adjustments in care plan • Ensure access for patients who need additional support	• Standardize documentation of glycemic targets for all patients • Appointments default to PCP (primary care physician)

Number/Area of Critical Pathway		Patient Changes	Care Team Changes	Health System Changes
4a	HbA1c target not achieved	• Reassess patient self confidence in managing diabetes • Assist with appropriate self-management goal setting and strategies to overcome barriers • Consider health literacy screening or depression screening • Implement support groups • Provide cooking classes and dietician guidance	• Assess current care plan, barriers to following care plan, and collaborate with patient on care plan modifications • Improve continuity; continuity typically improves care plan understanding and adherence	Consider more aggressive follow up standards for high risk patients – prompts for more aggressive follow-up
4b	Once the target is achieved, ensure that it can be maintained at target level *Note: Process starts over as indicated by arrow in Figure 4.2*	• Ask about any upcoming challenges and problem solve solutions • Actively support ongoing self-management issues	• Celebrate that value is at target • Document current treatment plan and share copy with the patient	Patient routinely given documentation of current care plan
5	Reinforce care guidelines and appropriate follow-up	Schedule self-management support between visits as indicated.	• Share clinical guidelines in patient-friendly format • Set clear expectations for follow-up	Ensure patient receives guidance about access to practice with interim concerns

This toolkit is meant as a guide to help organize ideas, but is also designed to allow flexibility for creative planning.

Note: An organization may choose to adapt and refine a tool to assist improvement for the measure, **Diabetes HbA1c**. Testing the measure before fully implementing it offers a way to try something new and modify it before additional resources are spent.

How Can an Organization Make Those Changes?

Earlier in this module, examples are provided of changes (Critical Pathway and Care Model) that have led to improved organizational systems of care and better patient health outcomes. Because every change is not necessarily an improvement, changes must be tested and studied to determine whether the change improves the quality of care. This concept is addressed in detail in the **Managing Data for Performance Improvement** module.

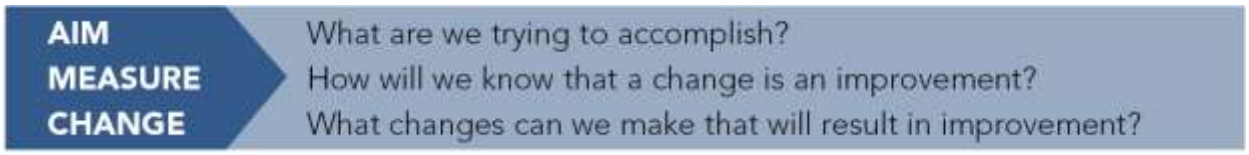
It is important that these changes be tested in the context of an organization's staff, current processes, and patients. The goal is that the change results in lasting improvements within an organization.

Organizations commonly use tools to manage change as they work to improve their systems. For further discussion on change management, refer to the **Redesigning a System of Care to Promote QI** module. Here are a couple of tools worth mentioning in the context of this measure:

1. Small tests of change – Model for Improvement and PDSA (Plan-Do-Study-Act)
2. Process mapping

1. Model for Improvement

The *Model for Improvement* identifies aim, measure, and change strategies by asking three questions:[15]



These questions are followed with learning cycles to plan and test changes in systems and processes, which are referred to as PDSA (Plan-Do-Study-Act) cycles. The PDSA Cycle is a test-and-learning method for discovering effective and efficient ways to change a current process. In **Figure 4.3**: **The PDSA Cycle**, the graphic provides a visual of the PDSA process:

Figure 4.3: The PDSA Cycle

An organization focusing its improvement efforts on **Diabetes HbA1c** for its patients benefits from implementing PDSAs to test change processes that have an impact on diabetic patient care. Those organizational processes tested may focus on outreach, operational procedures, or patient education interventions ensuring that patients have timely access to care. A few examples of such processes relating to **Diabetes HbA1c** are listed below:

- What system is in place to provide patients with timely reminders regarding HbA1c testing?
- What are the assigned roles, duties, and tasks for planned visits to a multidisciplinary care team? Are members of the team cross-trained?
- Does the patient population understand its specific role in managing its diabetes or is there an opportunity for education?
- Is there an opportunity to educate the community on the importance of adequate control for diabetes in a group visit setting?
- Are there cultural, linguistic, and literacy barriers that the organization may need to address?

As an organization plans to test a change, it should specify *who, what, where,* and *when* so that all staff know their roles clearly. Careful planning results in successful tests of change. Documentation of what happened – the *S* or study part of the PDSA – is also important. This can help a team understand the impact of changes to a process as unanticipated consequences may occur.

The case story continues...

PDSA Cycles in Action:

The team agreed to reflect on what it had learned from its observations and also read through the list of key changes that had worked for others. The team would decide where to focus its initial PDSAs at the next meeting. In addition, the MA was given more time to look through patient charts to ensure that all results had been captured. The team decided it was not worth changing the lab-filing procedure, but incoming lab results should be routed for data entry before they were filed. The team agreed to discuss PDSAs around that process at the next meeting.

As it turned out, the actual performance baseline was 42 percent, not 49 percent. The team still had a long way to go but felt more confident that its starting point was accurate. The team continued its work and focused PDSAs on areas that might benefit from change. It used resources to help guide it about changes that worked, and monitored its data over time. It developed standing orders for HbA1c and a more aggressive outreach program for no-shows, and tracked results received for labs ordered. Helping patients get their HbA1c's done when due resulted in considerable improvement, and at that point, only 25 percent of Dr. Harmon's patients had an HbA1c greater than 9 percent. The team next focused on barriers to improving glycemic control. Dr. Harmon attended a conference and learned how to more effectively use the newer insulin types with meals to improve glycemic control. He also changed his practice to be more aggressive to achieve glycemic control for his patients and not waiting for months of failed diet and exercise attempts. The dietician played a key role, especially as she and Dr. Harmon learned more about each other's approaches, and together were able to strategize about challenging patients. The organization adopted a policy of screening all patients with diabetes for depression. Several patients achieved glycemic control after their depression symptoms improved. The clinic also developed coaching for self-management support and considered shared medical visits.

Tips for Testing Changes

- Keep the changes small and continue testing.
- Involve care teams that have a strong interest in improving glycemic control.
- Study the results after each change. All changes are not improvements; do not continue testing something that does not work!
- If stuck, involve others who do the work even if they are not on the improvement team.

- Make sure that overall aims are improving; changes in one part of a complex system sometimes have an adverse effect in another.

2. Process Mapping

Process mapping is another valuable tool for an organization focused on improvement. A process map provides a visual diagram of a sequence of events that result in a particular outcome. Many organizations use this tool to evaluate a current process and again when restructuring a process.

The purpose of process mapping is to use diagramming to understand the current process; i.e., how a process currently works within the organization. By looking at the steps, their sequence, who performs each step, and how efficiently the process works, a team can often visualize opportunities for improvement.

Process mapping can be used before or in conjunction with a PDSA cycle. Often, mapping out the current process uncovers unwanted variation. Several staff may perform the process differently, or the process is changed on certain days or by specific providers. By looking at the process map, a team may be able to identify gaps and variation in the process that have an impact on glycemic control for diabetic patients.

Both of these improvement strategies are illustrated in the hypothetical scenario in **Example 4.1: Illustration of Improvement Strategies:**

Example 4.1: Illustration of Improvement Strategies

Successful Referral to a Diabetes Educator

At a small clinic in the northeast, the organization's improvement team found that 45 percent of its diabetic patients had an HbA1c of greater than 9 percent. Further investigation revealed that approximately over half of those patients had never had an appointment with the diabetes educator. The improvement team decided to look at the process of how those appointments were scheduled. The current process mapped by the improvement team was:

1. Diabetes educator appointment ordered by the provider at time of the patient's visit.
2. MA schedules an appointment at the hospital and provides information to the patient.
3. Documentation of patient visits with the diabetes educator or no-shows received by the health center.

The team felt that Steps 2 and 3 were potential problems in the process and analyzed how they could be improved. Phone calls were made to five patients who had been referred for diabetes education to assess their experiences. Two had attended their appointments but had difficulty finding the educator's office; two had not attended because they felt that it would not be worthwhile, and one developed a schedule conflict after the appointment had been made. There was no notation that the three patients had no-showed their appointments in the patients' charts.

The QI team considered various strategies, such as, providing clearer instructions for patients, providing education on site, and improving the feedback loop between the educator and the provider. The team investigated the option of contracting the diabetes educator for a half day per week to work on site and found that it could be reimbursed for her services. This arrangement was put in place as a three-month trial and referral completion rates were monitored monthly. Although attendance was not perfect, it was significantly better than when patients were referred off site. The team also emphasized that notes from the visit, or that the patient no-showed, was critical information that must be documented in the patient chart.

The team strategy was successful. By having the diabetes educator on site, access to the service was simplified and was perceived by patients to be more integrated with their providers' care.

Process mapping, when used effectively, can identify opportunities for improvement, and support testing changes in the current system of care. Additional information, including tools and resources to assist an organization in adapting process mapping as an improvement strategy within its organization, can be found in the **Redesigning a System of Care to Promote QI** module**.**

How Can an Organization Know the Changes Caused an Improvement?

Measures and data are necessary to answer this question. Data is needed to assess and understand the impact of changes designed to meet an organization's specified aim. Measurement is essential in order to be convinced the changes are leading to improvement. Organizations with successful improvement efforts found that data, when shared with staff and patients outside the core improvement team, led to the *spread of improvement* strategies, in turn generating interest and excitement in the overall quality improvement process.

Measures are collected prior to beginning the improvement process and continue on a regularly scheduled basis throughout the improvement program. Once an organization reaches its specified goal, frequency of data collection may be reduced. Additional information regarding

frequency of data collection, tracking, and analyzing data can be found in the **Managing Data for Performance Improvement** module**.**

Part 5: Holding the Gains and Spreading Improvement

Holding the Gains

Once an organization has redesigned the process for diabetes care regarding HbA1c, it can be tempting to move on to other issues and stop monitoring the process. Ongoing monitoring ensures that an organization *holds the gains* over time.

Although an organization may be able to reduce the frequency of monitoring the process, some ongoing assessment of the measure is necessary to ensure an organization continues to meet its intended goal. Processes that work well now may need to change as the environment shifts. Because all systems are dynamic, they change unless efforts are made to ensure that the improvements continue. Organizations often do a few simple things to ensure that successful changes are embedded in the daily work. Examples include:

1. Change the procedure book to reflect the new care process.
2. Include key tasks in the new process as part of job descriptions.
3. Adjust the expectations for performance to include attention to quality improvement and teamwork to improve care.
4. Re-align hiring procedures to recruit individuals who are flexible and committed to quality improvement.

The case story continues...

Sustaining Improvements:

A year later…

About 15 percent of Dr. Harmon's patients have their last HbA1 greater than 9 percent, and the team is working diligently to assist these patients. Even though the team is still working toward its aim, it has made considerable progress and learned much along the way. Because the results have been communicated at staff meetings, other providers are interested in adopting some of these changes that work and to follow the results in a registry. Confident it could make meaningful changes as a team, it expanded the team quality improvement project to include other metrics pertinent to excellent diabetes care. It used the NCQA Physician Recognition Program as a guide to choose measures and to develop appropriate aims. It remained focused on one care team to test changes to achieve its aim initially, but the organizational leadership was committed to do more; excellence in diabetes care across the organization became a strategic priority. Over the subsequent two years, the clinic made substantial improvement and is now known countywide for the excellence of its diabetes care.

Spreading Improvement

Spread can be defined differently based on an organization's target population for the improvement effort. An organization often begins an improvement intervention on a smaller scale, possibly focusing on one site or one provider's patient panel, and then increases the population of focus (POF) or the number of providers. Spread can mean spreading improvements to another area of an organization. An organization can still focus on glycemic control for diabetic patients but also include other or all providers that provide diabetes care. Ideally, others can learn from the initial improvement experience and implement the interventions of the improvement team in their own environments. Spread of this kind is often at an accelerated pace as there is experience about changes that work within the organization. Once it has successfully reached its goal for **Diabetes HbA1c**, an organization may choose another measure to improve other aspects of diabetes care. Good sources for diabetes measure sets include:

- NCQA
- NQF
- PQRI
- PCPI
- National Diabetes Quality Improvement Alliance

Another option is to target a different topic or another population of patients. An organization may evaluate organizational priorities as it did when initially choosing the **Diabetes HbA1c** measure and begin to plan for its next improvement effort. Additional information on *Holding the Gains* and *Spreading Improvements*, including specific resources and tools to support an organization's improvement program, can be found in the **Quality Improvement** module.

Part 6: Supporting Information

Case Story

To gain insight into how one QI team approached this measure, review a practical (albeit fictional) case story highlighting Healthy Valley Clinic's approach to improving **Diabetes HbA1c** performance.

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Additional Resources

1. American Diabetes Association www.diabetes.org General diabetes information.
2. Improving Chronic Illness Care www.improvingchroniccare.org Dedicated to sharing strategies for improving how care teams deliver care for chronic illness
3. Institute for Healthcare Improvement www.ihi.org General topics and strategies for improvement, including diabetes care.
4. Diabetes Training Manual http://www.healthdisparities.net/hdc/hdcsearch/?IW_DATABASE=library&IW_FIELD_TEXT=6-16-2005.3354+IN+documentidtbl